PUBLIC NOTICE

As the authority with substantive and territorial jurisdiction for stipulating metrological and technical requirements for legally controlled measuring instruments and stipulating test methods for type approval and verification of legally controlled measuring instruments pursuant to §14(1) of Act No 505/1990, on metrology, as amended (hereinafter the ‘Metrology Act’), and in accordance with the provisions of §172 et seq. of Act No 500/2004, the Code of Administrative Procedure (hereinafter the ‘CAP’), the Czech Metrology Institute (hereinafter the ‘CMI’) commenced ex officio proceedings on 22 January 2016 pursuant to §46 of the CAP, and based on supporting documents issues the following:

I.

DRAFT MEASURE OF A GENERAL NATURE

number: 0111-OOP-C040-16

laying down the metrological and technical requirements for legally controlled measuring instruments, including test methods for type approval and verification of the following legally controlled measuring instruments:

‘breathalysers’

1 Basic definitions

For the purposes of this Measure of a General Nature, the terms and definitions pursuant to VIM and VIML1) and the terms and definitions below shall apply.

1) International Vocabulary of Metrology – Basic and General Concepts and Associated Terms (VIM) and International Vocabulary of Terms in Legal Metrology (VIML) are part of the technical harmonisation compendium ‘Terminology in the Area of Metrology’, which is publicly accessible at www.unmz.cz.
1.1 breathalyser

a measuring instrument intended for determining the mass concentration of ethanol in air exhaled by the tested individual; detection takes place through a highly selective measurement method (e.g. an electrochemical cell, IR)

1.2 stationary breathalyser

a breathalyser intended for use inside buildings or on premises with stable ambient conditions

1.3 mobile breathalyser

a breathalyser intended for mobile applications (e.g. in a car)

1.4 portable breathalyser

a portable measuring instrument intended for outdoor or indoor use, e.g. a hand-held device powered by an autonomous battery, which may also be equipped with a separate mobile printer

1.5 breath alcohol measurement

determination of the mass concentration of ethanol in exhaled air generated in the pulmonary alveoli of the tested person, in mg/L

Under existing legislation in the Czech Republic, the results of this measurement method are converted by the analyser from breath alcohol concentration to blood alcohol concentration and expressed in units of ‰ (per mille) or g/kg (grams of alcohol per kilogram of blood).

NOTE Mass concentration of alcohol in breath is the proportion by mass of ethanol in a volume of exhaled air at a temperature of 34 °C and pressure of 1013 hPa. Mass concentration of alcohol in blood is the proportion by mass of ethanol in a volume (mass) of blood at a temperature of 20 °C and pressure of 1013 hPa.

According to Henry’s law, breath alcohol concentration (BrAC – breath alcohol concentration) depends on blood alcohol concentration (BAC – blood alcohol concentration). In the Czech Republic, breathalysers shall be adjusted to convert the value using the ratio BAC : BrAC = 2100 : 1. This ratio is statistically the most commonly used in European countries for determining the mass concentration of alcohol directly in units of ‰. This means that in the Czech Republic analysers shall be adjusted to use the ‰ (per mille) : mg/L conversion ratio of 2.1 : 1.

1.6 exhaled (alveolar) air

air contained in the alveoli, where the gaseous exchange takes place between the blood and gases contained within the alveoli
1.7 end expiratory breath

air considered sufficiently representative of alveolar air (as opposed to dead anatomical volume)

1.8 expiratory reserve volume

the volume of respiratory gases that can still be exhaled after normal expiration has occurred

1.9 residual lung volume

the volume of air that cannot be exhaled even with determined effort by the test subject to exhale completely

1.10 dead anatomical volume

airway volume up to the terminal bronchioles. It may be increased by the volume of alveoli that are incapable of respiratory gases exchange.

1.11 blood alcohol measurement

determination of mass concentration of ethanol in the blood in g/kg or in ‰ (per mille)

NOTE Devices for measuring breath alcohol concentration can express the mass concentration of ethanol determined in mg/L or convert this value using the analyser into mass concentration of alcohol in the blood in ‰ (per mille), for which a conversion constant of 2.1 is used in the Czech Republic.

1.12 breathalyser measuring mode

in this mode, the breathalyser provides results of measurements of breath alcohol concentration in the form of a specific numerical value in the desired units

1.13 breathalyser standby mode

a mode whereby only certain circuits are energised in order to conserve power and prolong the lifetime of the device’s individual components. In this mode, the device attains the measuring mode more rapidly than from the un-powered state.

1.14 breathalyser maintenance mode

a mode in which the device can be adjusted and is subject to metrological control
1.15 maintenance equipment

equipment used to configure the breathalyser when it is in maintenance mode

1.16 automatic check

an internal device or process that checks whether the breathalyser is suitably adjusted. This check may involve an internal checking element (stability or temperature check) or an external element, for example a cylinder with a gas of known concentration

1.17 drift

a change in indications that occurs after the passage of a certain amount of time between measurements at a given mass concentration of ethanol

1.18 memory effect

dependence of the value indicated by the measuring instrument on the value indicated by the same measuring instrument for the preceding sample

2 Metrological requirements

The metrological requirements are based on the requirements of Recommendation OIML R 126\(^2\) ‘Evidential breath analysers’ and standard ČSN EN 15964 Breath alcohol test devices other than single use devices - Requirements and test methods. During verification, measuring instruments type approved prior to the effective date of this regulation shall be subject to metrological requirements applicable at the time they were put into circulation.

NOTE If, for the sake of measurement accuracy, the number of measurements (analyses) or the period of time after which the breathalyser needs to be adjusted to reference values are limited, the manufacturer shall specify this time limit in the documentation for the measuring instrument and/or ensure that the measuring instrument directly signals that this limit has been reached.

2.1 Description of the measuring instrument and measurement

In general, determination of breath alcohol concentration consists of three stages: sampling, sample analysis, determination, presentation, storage and printing of the result.

2.1.1 Sampling

A disposable mouthpiece should always be used if during sampling the subject’s mouth or lips come into contact with the device. This allows hygienic handling of the device. Condensation of the sample shall be avoided during sampling.

2.1.2 Sample analysis

The ethanol concentration in the air exhaled from the pulmonary alveoli has to be determined. The analysis shall not be influenced by influences during sampling or by ambient conditions.

\(^2\) OIML R 126 e12 ‘Evidential breath analysers’, freely available at www.oiml.org
2.1.3 Determination, presentation, storage and printing of results

The determined ethanol concentration shall be indicated on the display of the device. Simultaneously, the measured value shall be stored in the device. It shall be possible to print the measurement result. For all display and storage methods, the result shall have the same format (e.g. the same decimal mark), along with all associated information (e.g. time and date). The entire user environment shall be in Czech and use Czech symbols.

2.1.4 Unit of measurement and decimal mark

The breathalyser shall provide results in units of mass concentration of alcohol in a specified volume of air. The unit of measurement shall be milligrams of ethanol per litre of exhaled air (mg/L). The device shall provide the option to switch the unit of measurement to mass blood ethanol concentration. The unit of measurement shall then be grams of ethanol per kilogram of blood (g/kg) or per mille (%).

Either a comma or a dot may be used as the decimal marker.

2.2 Measuring range

The measuring range of the breathalyser shall be specified by the manufacturer and shall be from 0.00 mg/L to at least 2.00 mg/L. The breathalyser shall be capable of indicating (including as a numerical value) that the upper limit of the measuring range has been exceeded.

2.3 Resolution

The resolution in measuring mode shall be 0.01 mg/L. If the device has a higher resolution, it shall round the result down to two decimal places. The value is always rounded down (e.g. a measurement result of 0.427 mg/L shall be rounded to 0.42 mg/L). In maintenance mode, it shall be possible to display the result with three decimal places; hence, the resolution has to be 0.001 mg/L. The name or symbol of the unit of measurement used shall be indicated on the display in close proximity to the numerical result of the measurement.

2.4 Preservation of metrological properties

The breathalyser shall be designed to maintain its metrological properties for the entire period of validity of verification.

2.5 Operating conditions

2.5.1 Operating conditions for using the measuring instrument

The breathalyser operating conditions are provided in Table 1. While all devices must meet these requirements, the manufacturer may apply for approval of operating conditions beyond the scope of the requirements stipulated in Table 1 for a specific type of measuring instrument. If, based on this application, the measuring instrument is approved for use beyond the use of operating conditions specified in Table 1, this fact shall be stated in the documentation for the given type of measuring instrument and on the device itself.

<table>
<thead>
<tr>
<th>Ambient temperature</th>
<th>Low</th>
<th>High</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>+5 °C for stationary breathalysers</td>
<td>+30 °C for stationary breathalysers</td>
</tr>
<tr>
<td></td>
<td>-5 °C for mobile breathalysers</td>
<td>+40 °C for mobile breathalysers</td>
</tr>
<tr>
<td></td>
<td>-5 °C for portable breathalysers</td>
<td>+40 °C for portable breathalysers</td>
</tr>
</tbody>
</table>
| Relative humidity | Devices shall be capable of measurement in humidity of up to 85 %.
|-------------------|------------------------------------------------------------------------|
| Atmospheric pressure | 860 hPa - 1060 hPa
| Random vibrations | Negligible for stationary breathalysers;  
Frequency range 10 Hz - 150 Hz  
RMS: 7 ms⁻²  
ASD 10 – 20 Hz: 1 m²s⁻³  
ASD 20 – 150 Hz: -3 dB/octave  
for mobile and portable breathalysers
| DC power voltage | According to manufacturer specifications  
Uₜₐ₉₉ - 15 % to Uₜₐ₉₉ + 10 %
| AC power voltage | fₕₐ₉₉ - 2 % to fₕₐ₉₉ + 2 %
| AC power frequency | The entire range of voltages between a new or freshly charged battery and the  
lowest voltage at which, according to the manufacturer’s specifications, the device is capable of operation
| Internal battery voltage |  
Vehicle battery voltage | 12 V battery | 9 V - 16 V  
24 V battery | 16 V - 32 V
| Ambient hydrocarbon concentration | ≥ 5 ppm

### 2.5.2 Exhalation parameters

If the exhalation parameters are not met, the breathalyser shall display an error message.

- Volume of exhaled air: 1.2 L  
- Flow: 6 L/min  
- Exhalation time: 5 s  
- Back pressure: 25 hPa (at a flow of 12 L/min)

### 2.5.3 Reference operating conditions

Reference operating conditions apply to ambient conditions in a laboratory where breathalysers are verified. Reference operating conditions are provided in Table 2.

<table>
<thead>
<tr>
<th>Table 2: Reference operating conditions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ambient temperature</td>
</tr>
<tr>
<td>Ambient pressure</td>
</tr>
<tr>
<td>Test gas flow</td>
</tr>
<tr>
<td>Gas volume</td>
</tr>
</tbody>
</table>

### 2.5.4 Warm-up time

Under reference conditions, the measuring instrument shall be capable of proper measurement:

- after a warm-up period specified by the manufacturer - not more than 15 minutes after the measuring instrument has been switched on,
- in less than 5 minutes after it has been switched from sleep (standby) mode to measuring mode.

If these requirements are not met, the relevant periods shall be clearly indicated on the measuring instrument and stated in the manufacturer’s documentation.

2.6 Maximum permissible error (MPE)

2.6.1 Maximum permissible error for type approval, verification and after repair

Maximum permissible errors (positive or negative) for each measurement are given in Table 3.

<table>
<thead>
<tr>
<th>Mass concentration of ethanol in exhaled air (mg/L)</th>
<th>Maximum permissible error (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.4</td>
<td>0.020</td>
</tr>
<tr>
<td>≤ 0.4 and ≥ 2.0</td>
<td>5 % *)</td>
</tr>
<tr>
<td>&gt; 2.0</td>
<td>(reference value/2) – 0.90</td>
</tr>
</tbody>
</table>

*) Values in percent are relative to the measured value of mass concentration of ethanol.

2.6.2 Maximum permissible error for the results of verification of legally controlled breathalysers

Table 4 - Limits for verification of legally controlled breathalysers

<table>
<thead>
<tr>
<th>Mass concentration of ethanol in exhaled air (mg/L)</th>
<th>Maximum permissible error (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.4</td>
<td>0.030</td>
</tr>
<tr>
<td>≤ 0.4 and ≥ 2.0</td>
<td>7.5 % *)</td>
</tr>
<tr>
<td>&gt; 2.0</td>
<td>reference value*(3/4) – 1.35</td>
</tr>
</tbody>
</table>

*) Values in percent are relative to the measured value of mass concentration of ethanol.

2.7 Repeatability of measurement

The repeatability of measurement expressed as the standard deviation of a given number of measurements. Repeatability is expressed mathematically by formula (1).

The maximum standard deviation for all concentrations shall not exceed one third of the maximum permissible error.

\[
S = \sqrt{\frac{\sum_{i=1}^{n} (Y_i - \bar{Y})^2}{n - 1}}
\]

(1)

Where:  
\( S \) standard deviation  
\( n \) number of measurements  
\( Y_i \) the \( i \)th measurement for the given concentration  
\( \bar{Y} \) the arithmetic mean of measured values
2.8 Drift
Zero drift and short-term drift at 0.40 mg/L shall be less than 0.010 mg/L in 4 hours.
Long-term drift at 0.40 mg/L shall be less than 0.020 mg/L in two months.

2.9 Memory effect
The memory effect shall be less than 0.010 mg/L.

2.10 Small changes in mass concentration of gas, residual effect
When alternately measuring two test gases, the measurement results for the test gas (CRM) with lower mass concentration shall not differ by more than 0.010 mg/L.

3 Technical requirements
The technical requirements are based on the requirements of Recommendation OIML R 1263) ‘Evidential breath analysers’. When verifying measuring instruments type approved prior to the effective date of this regulation, they shall be subject to technical requirements applicable at the time they were put into circulation.

3.1 In general
A portable breathalyser shall be designed for outdoor or indoor use and allow connection to a mobile printer.

If the breathalyser converts the calculated breath alcohol concentration value to per mille, the indicated value shall be a 2.1-multiple of the value in mg/L. (This value is accepted in European countries as the conversion factor for official purposes; the conversion error has been determined by experimental measurements and does not exceed 0.20 ‰ when converted into blood alcohol concentration).

The exhaled volume shall be at least 1.2 L and this value shall correspond to an exhalation time of at least 4 seconds. The minimum gas flow rate shall be 6 L/min.

The breathalyser shall perform a measurement only if the sample taken is a sample of alveolar air. The analyser shall in particular inhibit a measurement if the exhalation is discontinuous, or if the exhaled air is from the upper respiratory tract. In the case of discontinuous exhalation or exhalation from the upper respiratory tract, the measurement result shall not be indicated by the breathalyser as a numerical value.

The breathalyser shall inhibit a measurement if air is inhaled instead of exhaled. If air is inhaled instead of exhaled, the breathalyser shall not evaluate the measurement result as a numerical value.

Before each test, the measuring instrument shall make an automatic adjustment and check that it is capable of making a correct measurement. If this verification reveals that not all the conditions for correct operation of the breathalyser have been fulfilled, the breathalyser shall automatically inhibit measurement.

A breathalyser shall be used only with mouthpieces specified by the manufacturer and in compliance with the mouthpieces indicated for the particular approved measuring instrument type.

3.2 Printer
The measurement results at the printer output shall be identical to those shown on the display of the measuring instrument, including the symbol of the measurement unit used. In the case of portable
breathalysers, the printer shall be a separate part of the measuring instrument. A mobile printer shall be connected to the measuring instrument by a separate cable or wireless connection.

3.3 Software

Software critical for metrological properties shall be identifiable by the manufacturer as a separate, numbered version that conforms to the approved measuring instrument type. Software identification shall be possible in a simple manner while the measuring instrument is in routine operation. The installed software shall be secured by the manufacturer against accidental or unauthorised outside interference (e.g. by means of a maintenance password). If the software needs to be reinstalled (as part of measuring instrument maintenance), new verification of the measuring instrument’s metrological characteristics shall be conducted.

3.4 Physiological factors influencing measurement

If the exhaled air contains components of pharmaceuticals or products of abnormal human metabolism, or other gases, these substances may influence the measurement result. The extent of such influence shall not be greater than specified in Table 11 in Section 5.3.6, especially when assessed in relation to the limit below which the result of the breath alcohol content test is considered negative (i.e. if it does not exceed 0.20‰ when converted into blood alcohol concentration). Breathalysers shall be based on a highly selective measurement principle (e.g. an electrochemical cell, infrared spectrometry) that makes it impossible to identify another chemical substance as ethanol during measurement. Identification of the influence of interfering components is part of the test of the measuring instrument pursuant to Article 5.3.6.

3.5 Resistance to environmental influences

External disturbances affecting the breathalyser referred to in Chapters 3.5.1 and 3.5.2 shall not lead to measurement errors that would exceed the maximum permissible error of the breathalyser pursuant to Article 2.6.

If significant errors or significant faults occur, they shall be detected and reported by the checking facility contained in the breathalyser.

In such cases, the breathalyser shall not indicate the measurement result as a numerical value.

3.5.1 Resistance to mechanical influences

The design of the breathalyser and the materials used shall provide sufficient strength, stability, and immunity to mechanical vibrations and shocks.

3.5.2 Resistance to climatic influences

When switched off, breathalysers shall withstand, without damage, the limit temperatures of −20 °C and +70 °C, unless specified otherwise by the manufacturer. After returning to the operating temperature range, they shall operate within the limits of the maximum permissible error.

Breathalysers shall not be sensitive to relative ambient humidity, whether in operation or while in storage.

3.5.3 Electromagnetic compatibility (EMC)

Breathalysers may not be affected by electrical or electromagnetic interference or they shall respond to it in a certain specific manner, e.g. by reporting an error, inhibiting measurement, etc. They shall not emit unwanted electromagnetic fields.

When tested for electromagnetic compatibility in a laboratory, the breathalyser shall function normally. Measuring instrument restart as a response to interference is permitted.
3.6 Supply voltage
Breathalysers powered by DC from a battery shall operate normally within at least the voltage range specified by the manufacturer ($U_{\min}$ to $U_{\max}$). When outside of this specified supply voltage range, the measuring instrument shall switch itself off or switch to a mode in which measurement is not possible.

3.7 Resistance to unauthorised tampering
The breathalyser shall be designed such that any mechanical actions performed on this measuring instrument that may influence measurement accuracy will result in permanent visible damage to the measuring instrument or official marks.

4 Markings
All of the information below indicated on the breathalyser shall be indelible, non-removable and legible throughout the entire period of use.

4.1 Labelling of breathalysers
Every breathalyser shall indicate at least the following information:
- the manufacturer’s insignia or name,
- the type approval mark of the measuring instrument,
- the serial number and year of manufacture*)
- measuring range in mg/L,
- ambient operating temperature range in °C.

*) The device’s serial number shall also be easy to identify in its menu.

5 Type approval

5.1 In general

5.1.1 Tests to be performed
The type approval of a breathalyser shall comprise the following:
- external inspection,
- functional tests of the breathalyser:
  - an accuracy and repeatability test,
  - a test of zero drift, short-term and long-term drift,
  - a memory effect test,
  - a residual effect test,
  - a test of volume influence (flow rate change),
  - a test of influence of interfering components and CO₂,
- tests of resistance to mechanical influence:
  - an impact resistance test,
  - a free-fall test,
– a test of influence of random mechanical vibrations,

d) tests of resistance to climatic conditions:
   – a cold test (in both off and on mode),
   – a dry heat test,
   – a damp heat test (in both off and on mode),

e) a test of influence of supply voltage,

f) tests for electromagnetic compatibility (EMC):
   – an electrostatic discharge immunity test,
   – a test of immunity to radiated high-frequency electromagnetic fields,
   – a test of immunity to TETRA signals.

5.1.2 Test equipment
The measuring instruments, certified reference materials and equipment specified below shall be used for testing breathalysers:

– certified reference materials (CRM);

Gas mixtures of the required composition (see Table 5) shall be used; these shall be primary reference materials - gas mixtures or secondary CRM - gas mixtures traceable to a suitable primary certified reference material. If needed, prior to type approval, the device shall be set to the mass concentration recommended by the measuring instrument’s manufacturer. The mole fractions of the certified reference gases shall be converted to mass concentrations at 34 °C at atmospheric pressure.

<table>
<thead>
<tr>
<th>CRM No</th>
<th>Mass concentration of ethanol in nitrogen (mg/L)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.04</td>
</tr>
<tr>
<td>2</td>
<td>0.10</td>
</tr>
<tr>
<td>3</td>
<td>0.25</td>
</tr>
<tr>
<td>4</td>
<td>0.40</td>
</tr>
<tr>
<td>5</td>
<td>0.70</td>
</tr>
<tr>
<td>6</td>
<td>0.95</td>
</tr>
<tr>
<td>7</td>
<td>1.50</td>
</tr>
<tr>
<td>8</td>
<td>1.95</td>
</tr>
<tr>
<td>9</td>
<td>90% of the maximum range in mg/L</td>
</tr>
</tbody>
</table>

Expanded uncertainty values of the CRM for ethanol in nitrogen shall not exceed 2 % (with a coverage factor of \( k = 2 \)). The manufacturing tolerance for the mass concentration of ethanol in the reference materials shall be ±15 %.

– a flow meter with a measuring range of at least 0 L/s to 0.40 L/s,
– a stopwatch with an accuracy of 0.1 s,
– a thermo-hygro-barometer for monitoring laboratory conditions,
– reducing valves with adjustable output gas pressure,
– test equipment for connecting and measuring the breathalyser.

5.2 External inspection

The following is assessed during an external inspection of the breathalyser:

a) the completeness of the prescribed technical documentation, including operating instructions,

b) the conformity of the metrological and technical characteristics specified by the manufacturer in the documentation with the requirements of this regulation specified in chapters 2, 3, and 4,

c) the completeness and condition of the breathalyser according to the prescribed technical documentation,

d) conformity of the software version of the breathalyser with the version specified by the manufacturer.

5.3 Breathalyser functional tests

Prior to the test, the breath alcohol analyser shall be warmed up in accordance with the requirements of Article 2.5.4. The functional tests themselves shall be performed under the reference conditions specified in Article 2.5.3.

Gas mixtures of the specified composition shall be fed into the breathalyser from cylinders with CRMs for gas mixtures, as per Table 5. Measurements shall be made sequentially from gas mixtures with lower mass concentrations to mixtures with higher mass concentrations. At the beginning and end of measurement, i.e. after the measurement for the highest mass concentration (90% of the max. range in mg/L of ethanol in nitrogen) has been made, a ‘zero’ check shall be performed using a ‘zero’ gas, which is nitrogen in a cylinder with a purity of at least 4.0 (99.99%).

Evacuation of gases from the device connected to the cylinders with the CRMs for the gas mixtures (see Table 5) and the ‘zero’ gas needs to be ensured during operations.

5.3.1 Accuracy and repeatability test

This test involves 20 measurements for each of the nine mass concentrations within the measuring range (nominal values: 0.04 mg/L, 0.10 mg/L, 0.25 mg/L, 0.40 mg/L, 0.70 mg/L, 0.95 mg/L, 1.50 mg/L, 1.95 mg/L and 90% of the upper limit of the measurement range for the given measuring instrument type).

After completing measurement, the average mass concentration value $\bar{\beta}$ shall be calculated according to formula (2):

$$\bar{\beta} = \frac{\sum_{i=1}^{n} \beta_i}{n}$$

(2)

where

$\bar{\beta}$ is the average mass concentration value

$\beta_i$ are the individual ethanol mass concentration values measured by the breathalyser when measuring gaseous CRM,

$n$ is the number of measured values, i.e. 20.

The deviation of the measured value from the certified value of ethanol in the gaseous CRM shall be less or equal to the maximum permissible value according to Table 3 in Article 2.6, where evaluation takes into account the uncertainty of the measured value and the uncertainty of the certified mass concentration of ethanol in the measured gaseous CRM:
Measure of a General Nature No 0111-OOP-C040-13

\[ |\bar{\beta} - \beta_{RM}| + 2 \cdot \sqrt{u_c(\bar{\beta})^2 + u(\beta_{RM})^2} \leq \text{MPE} \]

where

\( \bar{\beta} \) is the arithmetic mean of the measured values of mass concentration of ethanol when measuring the gaseous CRM,

\( u_c(\bar{\beta}) \) is the combined standard uncertainty,

\( \beta_{RM} \) is the mass concentration of ethanol in the measured gaseous CRM,

\( u(\beta_{RM}) \) is the standard uncertainty (obtained from expanded uncertainty using a coverage factor of \( k = 2 \)).

\( \text{MPE} \) is the maximum permissible error of the breathalyser for the given measurement conditions and mass concentration of ethanol in the CRM (see Table 5).

In order to assess repeatability, the standard deviation \( SD \) is calculated, which shall not be greater than one third of the maximum permissible error according to Table 3 in Article 2.6.1 for the given mass concentration. To calculate the standard deviation \( SD \), the following relationship holds:

\[
SD = \sqrt{\frac{\sum_{i=1}^{n} (\beta_i - \bar{\beta})^2}{n-1}}
\]

where

\( SD \) is the standard deviation

\( \bar{\beta} \) is the arithmetic mean of the measured values of mass concentration of ethanol when measuring the gaseous CRM,

\( \beta_i \) is the measured value.

Table 6 may be used to record and evaluate the test.

### Table 6 - Accuracy and repeatability test

<table>
<thead>
<tr>
<th>Reference mass concentration ((\beta_{RM}))</th>
<th>0.04 mg/L</th>
<th>0.10 mg/L</th>
<th>0.25 mg/L</th>
<th>0.40 mg/L</th>
<th>0.70 mg/L</th>
<th>0.95 mg/L</th>
<th>1.50 mg/L</th>
<th>1.95 mg/L</th>
<th>90 % of max. range mg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Accuracy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Average mass concentration ((\bar{\beta}))</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Determined error difference (</td>
<td>\bar{\beta} - \beta_{RM}</td>
<td>)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( U (k = 2) )</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum permissible error</td>
<td>&lt; 0.020 mg/L</td>
<td>&lt; 0.020 mg/L</td>
<td>&lt; 0.020 mg/L</td>
<td>5 %</td>
<td>5 %</td>
<td>5 %</td>
<td>5 %</td>
<td>5 %</td>
<td>(reference value/2) – 0.90 mg/L</td>
</tr>
<tr>
<td><strong>Repeatability</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Standard deviation ((SD))</td>
<td></td>
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<td></td>
<td></td>
</tr>
</tbody>
</table>
5.3.2 Drift test and long-term and short-term drift tests

The device stability test shall consist of three parts - drift, short-term drift, and long-term drift. The drift and short-term drift tests shall involve ten measurements of a test gas repeated after four hours. Measurements with the zero gas (no ethanol content) and test gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 3, CRM No 4) for drift and for short-term stability shall follow the procedure below:

- ten measurements with the zero gas - 4-hour break - ten measurements with the zero gas,
- ten measurements with the test gas - 4-hour break - ten measurements with the test gas.

The drift obtained from both measurements shall meet the requirements of Article 2.5.

Long-term drift is monitored in the same way as short-term stability, but the subsequent measurement using the test gas shall be made after two months; the requirement of Article 2.8 for maximum permissible drift of 0.020 mg/L shall be met. Table 7 may be used to record and evaluate this test.

Table 7 Drift and short-term and long-term drift

<table>
<thead>
<tr>
<th>Measurement number</th>
<th>Zero gas</th>
<th>Test gas 0.40 mg/L</th>
<th>Test gas 0.40 mg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>measurement time</td>
<td>measurement time + 4 h</td>
<td>measurement time</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean value</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Drift</td>
<td>Max. permissible drift</td>
<td>0.01 mg/L</td>
<td>0.01 mg/L</td>
</tr>
</tbody>
</table>

5.3.3 Memory effect test

The memory effect test shall be performed using the following procedure:

Step 1: ten measurements shall be performed with a mass concentration of 0.10 mg/L ethanol in nitrogen (see Table 5, CRM No 2),

Step 2: alternating measurements shall be performed using gas with mass concentration of 1.95 mg/L ethanol in nitrogen (see Table 5, CRM No 8) or 1.50 mg/L ethanol in nitrogen (see Table 5, CRM No 7), for measuring instruments with a range up to 2 mg/L, and measurements using gas with mass concentration of 0.10 mg/L of ethanol in nitrogen (see Table 5, CRM No 2).

Step 2 shall be repeated ten times, resulting in ten measured values at a high mass concentration and ten measured values at a low mass concentration. The memory effect shall meet the requirements of Article 2.9.

Every individual measurement shall comply with the maximum permissible error for the given mass concentration pursuant to Article 2.6. Table 8 may be used to record and evaluate this test.
### Table 8 - Memory effect

<table>
<thead>
<tr>
<th>Measurement number</th>
<th>Pre-test 0.10 mg/L (Step 1)</th>
<th>Alternating measurement of two concentrations (Step 2)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1.95 mg/L or (1.50 mg/L)</td>
<td>0.10 mg/L</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean value</td>
<td>$\beta_1$</td>
<td>- - -</td>
</tr>
<tr>
<td>Difference ($\beta_1 - \beta_2$)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 5.3.4 Residual effect test

The residual effect test shall be performed using the following procedure:

- **Step 1**: ten measurements shall be performed with a mass concentration of 0.25 mg/L ethanol in nitrogen (see Table 5, CRM No 3),
- **Step 2**: alternating measurements shall be performed using gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4) and using gas with mass concentration of 0.25 mg/L of ethanol in nitrogen (see Table 5, CRM No 3).

Step 2 is repeated ten times resulting in ten measured values measured at the higher mass concentration and ten measured values at the lower mass concentration.

The residual effect shall meet the requirements of Article 2.10. Every individual measurement shall comply with the maximum permissible error for the given mass concentration pursuant to Article 2.6. Table 9 may be used to record and evaluate this test.

### Table 9 - Residual effect

<table>
<thead>
<tr>
<th>Measurement number</th>
<th>Pre-test 0.25 mg/L</th>
<th>Alternating measurement of two concentrations</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.40 mg/L</td>
<td>0.25 mg/L</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td></td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>$\beta_1$</td>
<td>$\beta_2$</td>
</tr>
<tr>
<td>Difference ($\beta_1 - \beta_2$)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 5.3.5 Test of volume influence (flow rate change)

The influence of the gas inflow volume shall be tested using a test gas with a mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4) at gas volumes of 1.5 L and 3 L and flow rates of 0.20 L/s to 0.35 L/s. The difference between measurements shall not exceed 0.010 mg/L. Each of these ten measurements shall comply with the maximum permissible error for the given mass concentration pursuant to Article 2.6. Table 10A may be used to record and evaluate this test.

### Table 10A - Volume influence (flow rate change)

<table>
<thead>
<tr>
<th>Measurement number</th>
<th>Gas volume of 1.5 L</th>
<th>Gas volume of 3 L</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>...</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
If the breathalyser checks the volume of exhaled air automatically, measurements at higher volumes of exhaled air are irrelevant.

In such a case, measurements shall be performed using a test gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4) at a flow rate within the maximum range of 0.15 L/s to 0.40 L/s or at the minimum gas flow rate possible (0.15 to 0.20) L/s and two higher flow rates of the reference gas (0.25 to 0.30) L/s and (0.35 to 0.40) L/s. Ten measurements shall be performed at each chosen gas flow rate. Again, the difference between measurements shall not exceed 0.010 mg/L. Each of these ten measurements shall comply with the maximum permissible error for the given mass concentration pursuant to Article 2.6. Table 10B may be used to record and evaluate this test.

<table>
<thead>
<tr>
<th>Measurement number</th>
<th>gas flow rate (0.15 to 0.20) L/s</th>
<th>gas flow rate (0.25 to 0.30) L/s</th>
<th>gas flow rate (0.35 to 0.40) L/s</th>
<th>Difference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>10</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max. difference</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

5.3.6 Test of influence of interfering components and CO2

This test shall be performed to check compliance with Article 3.4 by means of ten measurements using dry gas with a mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4) without and with the interfering component. The maximum influence of a given interfering component shall not exceed the values specified in Table 11 and the sum of all specified interfering components and CO2 shall not exceed 0.40 mg/L. Table 11 may be used to record and evaluate this test.

<table>
<thead>
<tr>
<th>Interfering component (±5 %)</th>
<th>Acetone 0.50 mg/L</th>
<th>Methanol 0.10 mg/L</th>
<th>Isopropanol 0.10 mg/L</th>
<th>CO 0.20 mg/L</th>
<th>Toluene 0.20 mg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement using pure gas</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Measurement with the interfering component</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Influence</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Max. influence</td>
<td>0.05 mg/L</td>
<td>0.10 mg/L</td>
<td>0.10 mg/L</td>
<td>0.08 mg/L</td>
<td>0.08 mg/L</td>
</tr>
</tbody>
</table>

(continued)

<table>
<thead>
<tr>
<th>Interfering component (±5 %)</th>
<th>Methane 0.30 mg/L</th>
<th>Acetaldehyde 0.15 mg/Ls</th>
<th>CO2 100 mg/L</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Measurement using pure gas</td>
<td></td>
<td></td>
<td></td>
<td>–</td>
</tr>
<tr>
<td>Measurement with the interfering component</td>
<td></td>
<td></td>
<td></td>
<td>–</td>
</tr>
</tbody>
</table>

(continued)
5.4 Tests of resistance to mechanical influences

5.4.1 Shock resistance test
This test to check compliance with the requirements of Article 3.5.1 shall be performed on the breathalyser without a carrying case under the following conditions:

– every shock shall have an intensity of 10 g, where acceleration $1 \text{ g} = 9.81 \text{ m/s}^2$,
– duration: 6 ms,
– frequency: 2 Hz,
– number of shakes: 1000 in each axis perpendicular to the sample.

When at least two hours have elapsed after completion of the test, the measuring instrument shall meet the requirements specified in Article 2.6 when tested within the operating temperature range.

5.4.2 Free-fall test
During the free-fall test applied to check compliance with the requirements of Article 3.5.1, the breathalyser under test shall be allowed to fall freely from a height of 500 mm on a rigid test pad. The measuring instrument shall be allowed to fall on three sides: on its rear and on its right and left side. The test shall not be performed for the front side (where the display is located). The test shall be repeated two times for each side of the measuring instrument, i.e. a total of six free falls.

Immediately after the free falls, the measuring instrument is checked for changes in appearance. No changes in indication may occur during the test. After at least one hour has passed since the completion of the test, the measuring instrument shall comply with the requirements of Article 2.6 in an accuracy test at reference temperature.

5.4.3 Test of influence of random mechanical vibrations
In this test of compliance with the requirements of Article 3.5.1, the measuring instrument shall be exposed to broadband vibrations in three perpendicular axes under the following conditions:

– frequency range from 10 Hz to 150 Hz,
– spectral density of acceleration from 10 Hz to 20 Hz: 0.02 g²/Hz,
– spectral density of acceleration from 20 Hz to 150 Hz: -3 dB per octave,
– duration of 5 minutes in each axis.

After at least one hour has passed since the completion of the test, the measuring instrument shall comply with the requirements of Article 2.6 in an accuracy test at reference temperature.

5.5 Tests of resistance to climatic conditions

5.5.1 Cold test
The breathalyser in on-mode shall be placed in a temperature chamber at a temperature of $-5 \degree C$. Under these climactic conditions, an accuracy test shall be performed ten times using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4). Each of these ten measurements shall comply with the maximum permissible error for the given mass concentration pursuant to Article 2.6.

<table>
<thead>
<tr>
<th>Influence</th>
<th>0.08 mg/L</th>
<th>0.10 mg/L</th>
<th>0.05 mg/L</th>
<th>0.40 mg/L</th>
</tr>
</thead>
<tbody>
<tr>
<td>Max. influence</td>
<td>0.08 mg/L</td>
<td>0.10 mg/L</td>
<td>0.05 mg/L</td>
<td>0.40 mg/L</td>
</tr>
</tbody>
</table>
5.5.2 Dry heat test
The breathalyser in on-mode shall be placed in a temperature chamber at a temperature of +40 °C. Under these climactic conditions, an accuracy test shall be performed ten times using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4). Each of these ten measurements shall comply with the maximum permissible error for the given mass concentration pursuant to Article 2.6.

5.5.3 Damp heat test
a) A cyclic damp heat test (a 12 h + 12 h cycle) shall be performed using two cycles within a temperature range of 25 °C at a relative humidity above 95 % to 55 °C at a relative humidity of 93 %. The measuring instrument shall be switched off during the test.

The measuring instrument shall be inspected for changes in appearance immediately after the test. When one hour has passed after the completion of the test and the measuring instrument stabilised at 20 °C, shall comply with the requirements of Article 2.6 at the reference temperature in an accuracy test using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4).

b) The damp heat test shall be performed at 20 °C at a relative humidity of 85 %. The measuring instrument shall be switched on during the test. Under these climactic conditions, an accuracy test shall be performed ten times using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4). Each of these ten measurements shall comply with the maximum permissible error for the given mass concentration pursuant to Article 2.6.

5.5.4 Test of storage conditions
a) The test of influence of storage conditions shall be performed within a temperature range of -25 °C to +70 °C. The device shall first be placed in a chamber at -25 °C, where it shall be kept for 6 hours. After the measuring instrument is removed from the chamber, it shall be allowed to stabilise under the reference conditions specified in Chapter 2.5.5 and five measurements shall be performed using CRM No 4.

b) In the high temperature test, the measuring instrument shall be exposed to a temperature of +70 °C for 6 hours, after which it shall be removed from the chamber. After the measuring instrument is removed from the chamber, it shall be allowed to stabilise under reference conditions for one hour and five measurements shall be performed using CRM No 4.

The measuring instrument shall be inspected for changes in appearance immediately after the test. All ten measurements shall comply with the maximum permissible error for the given mass concentration pursuant to Article 2.6.

5.6 Test of supply voltage influence
The test of supply voltage influence shall be performed for battery-powered breathalysers with the supply voltage set at $U_{\text{max}} = U_{\text{bat,max}}$ and then at $U_{\text{min}} = U_{\text{bat,min}}$ for measuring instruments, where $U_{\text{bat.min}}$ is the battery’s lowest operating voltage, as specified by the measuring instrument’s supplier for an ambient temperature of 20 °C and $U_{\text{bat,max}}$ is the voltage of a new battery under zero load.

In an accuracy test using a dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4), the measuring instrument shall exhibit normal functionality within the limits of the maximum permissible error specified in Article 2.6.
5.7 Electromagnetic compatibility (EMC) tests

5.7.1 Test of immunity to electrostatic discharge

Immunity to electrostatic discharge shall be tested with the measuring instrument switched on, preferably using a 6 kV contact discharge or an 8 kV air discharge where contact discharge cannot be used. The discharges shall be applied to the enclosure of the measuring instrument or a coupling plane adjacent to the breathalyser.

During the test, ten measurements shall be performed using test gas for each discharge voltage polarity. One discharge shall be applied during each measurement. The delay between discharges shall be at least 10 s.

The difference between the values obtained under the conditions of interference and those without interference shall be less than 0.040 mg/l when using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4).

After this test, the measuring instrument shall exhibit normal functionality within the limits of the maximum permissible error specified in Article 2.6 in an accuracy test without interference using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4).

5.7.2 Test of immunity to high-frequency electromagnetic field radiation

Immunity to a radiated radio-frequency electromagnetic field shall be tested with the measuring instrument switched on, within the frequency range of 26 MHz to 3 000 MHz at a test field intensity of 10 V/m when measuring without modulation.

The test field shall be amplitude-modulated to a depth of 80 %; the modulation signal shall have a sinusoidal waveform with a modulation frequency of 1 kHz.

The tested measuring instrument shall be irradiated vertically and horizontally with a polarised field from four mutually perpendicular directions.

The test shall be performed at the following frequencies: (26, 40, 60, 80, 100, 120, 144, 150, 160, 180, 200, 250, 350, 400, 435, 500, 600, 700, 800, 934, 960, 1 000, 1 200, 1 400, 1 700, 1 800, 1 900, 2 000, 2 400, 2 700 and 3 000) MHz. One measurement using test gas shall be performed at each frequency.

If the measuring instrument is found to have been influenced at any of these frequencies, testing shall be performed in the region of this frequency to locate the point of maximum influence at a frequency resolution of approximately 1 %.

The difference between the values obtained under the conditions of interference and those without interference shall be less than 0.040 mg/l when using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4).

After this test, the measuring instrument shall exhibit normal functionality within the limits of the maximum permissible error specified in Article 2.6 in an accuracy test without interference using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4).

5.7.3 Test of immunity to TETRA system signals

Immunity to TETRA system signals shall be tested with the measuring instrument switched on by irradiating it using a field with vertical and horizontal polarisation sequentially in four mutually perpendicular directions.

The breathalyser shall be tested using at test frequencies (380, 385, 390, 395, 400, 405, 410, 415 and 420) MHz ±0.1 MHz.

At each frequency, the test field intensity shall be gradually increased in 3 dB steps from 12 dB below the set test limit until the test limit is reached. The level at which any influence is observed to begin to develop shall be recorded and included in the test report.
The test limit is given as the peak value of a modulated signal measured using a peak value detector calibrated according to the equivalent effective value of the sinusoidal signal causing the same deflection. The test limit for devices not used inside vehicles shall be 65 V/m.

For tests of immunity to TETRA system signals, amplitude modulation using a square-wave signal with a frequency of 18 kHz and modulation depth of > 98%, further keyed with a frequency of 17 Hz, shall be used. The keying duty cycle shall be 50 %.

The difference between the values obtained under the conditions of interference and those without interference shall be less than 0.040 mg/l when using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4).

After this test, the measuring instrument shall exhibit normal functionality within the limits of the maximum permissible error specified in Article 2.6 in an accuracy test without interference using dry gas with mass concentration of 0.40 mg/L ethanol in nitrogen (see Table 5, CRM No 4).

6 Initial verification

6.1 In general

6.1.1 Tests to be performed

The initial verification process for breathalysers shall comprise the following tests:

a) visual inspection,
b) an accuracy test.

6.1.2 Test equipment

The same measuring instruments and equipment as that used for type approval pursuant to Article 5.1.2 shall be used for initial verification tests of breathalysers. In addition, secondary CRM for ethanol in nitrogen traceable to a suitable primary reference material for the relevant gas mixture mole (mass) fractions according to Table 12 shall be used.

Table 12 - Certified reference materials

<table>
<thead>
<tr>
<th>CRM No</th>
<th>Mass concentration of ethanol in nitrogen (mg/L)</th>
<th>Number of measurements using the given gas</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>0.14</td>
<td>10</td>
</tr>
<tr>
<td>2</td>
<td>0.48</td>
<td>10</td>
</tr>
<tr>
<td>3</td>
<td>0.90</td>
<td>5</td>
</tr>
<tr>
<td>4</td>
<td>1.40</td>
<td>5</td>
</tr>
</tbody>
</table>

6.2 Visual inspection

The purpose of visual inspection shall be to assess that:

a) the measuring instrument submitted for verification conforms to the approved type,
b) the measuring instrument is complete and undamaged,
c) markings and inscriptions are complete, accurate and legible, in conformity with the approved type of the measuring instrument
d) the software version installed is the same as that specified by the manufacturer and conform to the approved measuring instrument type.
6.3 Accuracy and repeatability test

During initial verification, the breathalyser test shall be performed pursuant to the requirements of Articles 5.3 and 5.3.1 and the CRM used and the number of tests using a given gas shall be as specified in Table 12 in Article 6.1.2.

The combined standard uncertainty of this arithmetic mean of mass concentration $\bar{\beta}$ consists of standard uncertainty evaluated using method A $u_A(\bar{\beta})$ and standard uncertainty evaluated using method B $u_B(\bar{\beta})$:

$$u_C(\bar{\beta}) = \sqrt{u_A(\bar{\beta})^2 + u_B(\bar{\beta})^2}$$

Standard uncertainty evaluated using method A shall be calculated from the standard deviation of the arithmetic mean multiplied by a coefficient dependent on the number of measurements:

$$u_A(\bar{\beta}) = k_l \cdot s_A$$

where $k_l$ is the coefficient dependent on the number of measurements $n$:

<table>
<thead>
<tr>
<th>$n$</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
<th>7</th>
<th>8</th>
<th>9</th>
<th>10 or more</th>
</tr>
</thead>
<tbody>
<tr>
<td>$k_l$</td>
<td>7.0</td>
<td>2.3</td>
<td>1.7</td>
<td>1.4</td>
<td>1.3</td>
<td>1.3</td>
<td>1.2</td>
<td>1.2</td>
<td>1.0</td>
</tr>
</tbody>
</table>

$s_A$ standard deviation of the arithmetic mean,

$$s_A = \sqrt{\frac{\sum_{i=1}^{n}(\beta_i - \bar{\beta})^2}{n(n-1)}}$$

where

$\bar{\beta}$ is the arithmetic mean of the mass concentrations of ethanol obtained when measuring the gaseous CRM,

$\beta_i$ is the value obtained,

$n$ is the number of measurements.

NOTE Type B uncertainty of the values obtained is given by the uncertainty of the certified content of CRM used when configuring the breathalyser, the uncertainty caused by non-linearity, indication uncertainty, and in some cases uncertainty of the influence of deviation of the true temperature of exhalation into the analyser from 34 °C (determined during type approval of the measuring instrument), the influence of sensitivity to other gas components, influence due to changes in barometric pressure (if the measuring instrument does not provide for automatic correction), influence of changes in calibration gas flow rate, influence of other factors related to various principles of the measuring instrument used, etc.

For the purposes of verification and to ensure unambiguous and correct assessment of the breathalyser, type B uncertainty shall be estimated only from the standard uncertainty of the mass concentration of ethanol in the measured gaseous CRM $u(\beta_{RM})$ and the standard uncertainty of display resolution $u_{ind}$:

$$u_B(\bar{\beta}) = \sqrt{u(\beta_{RM})^2 + u_{ind}^2}$$

where

$u(\beta_{RM})$ is the standard uncertainty of mass concentration of ethanol in the measured gaseous CRM (obtained, for example, from expanded uncertainty with coverage factor $k = 2$),
$u_{\text{ind}}$ is the standard uncertainty of measuring instrument display (rounding):

$$u_{\text{ind}} = \frac{r_{\text{ind}}}{2\sqrt{3}}$$

where

$r_{\text{ind}}$ is the resolution of values read from the breathalyser display.

Other measured value uncertainties that play a role in the standard uncertainty evaluated using method B need not be specified during verification.

### 6.4 Correct measuring instrument configuration

The analyser delivered for verification by the customer shall be correctly configured, with minimal standard uncertainty of measured values. Otherwise, prior to measuring instrument verification, the breathalyser shall be configured for reference values.

### 7 Subsequent verification

A procedure identical to initial verification pursuant to Chapter 6 shall be applied during subsequent verification.

### 8 Notified standards

For the purposes of specifying metrological and technical requirements for measuring instruments and specifying the type approval and verification testing methods stemming from this measure of a general nature, the CMI shall provide notification of Czech technical standards, other technical standards or technical documents of international or foreign organisations or other technical documents containing detailed technical requirements (hereinafter ‘notified standards’). The CMI shall publish a list of these notified standards attached to the relevant measures, together with the measure of a general nature in a manner accessible to the public (on the www.cmi.cz website).

Compliance with notified standards or parts thereof is considered, to the extent and under the conditions stipulated by this Measure of a General Nature, to be compliance with those requirements stipulated by this measure to which these standards or parts thereof apply.

### II. REPEALING AND TRANSITIONAL PROVISIONS

Measure of a General Nature number: 0111-OOP-C040-13, stipulating metrological and technical requirements for legally controlled measuring instruments, including test methods for verification of legally controlled measuring instruments: ‘breathalysers’ is hereby repealed. The notified standards remain in force.

### III. G R O U N D S

Pursuant to § 14(1)(j) of the Metrology Act, the CMI has issued this Measure of a General Nature to implement § 6(2), § 9(1) and (9), and § 11a(3) of the Metrology Act, laying down metrological and technical requirements for legally controlled measuring instruments and tests for type approval and verification of legally controlled measuring instruments - ‘breathalysers’.
Under item 7.4.2 in the Annex ‘List of the Types of Legally Controlled Measuring Instruments’ to Implementing Decree No 345/2002 specifying the measuring instruments whose verification is mandatory and measuring instruments subject to type approval, as amended, this type of measuring instruments is classified as measuring instruments subject to mandatory verification.

This legislation (Measure of a General Nature) will be notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

IV.

INSTRUCTIONS

In accordance with § 172(1), in conjunction with § 39(1) of the APC, the CMI has stipulated a time limit for comments of 30 days from the posting of the draft. Comments submitted after this time limit will not be considered.

The persons concerned are hereby invited to comment on this draft Measure of a General Nature. With a view to the provisions of § 172(4) of the APC, the comments shall be submitted in writing and meet the requirements for submissions in accordance with § 37 of the APC.

The comments shall include the particulars referred to in § 37(2) of the APC, stating clearly who is making the comments, which measure of a general nature they concern, to what extent the comments challenge the measure, how it contradicts legislation or how the measure of a general nature or the procedure that preceded it is inaccurate, which matters the comments concern and what is being proposed; they must also identify the administrative authority to which they are addressed and be signed by the person making them.

The supporting documents for this draft Measure of a General Nature may be consulted at the Czech Metrological Institute, Department of Legal Metrology, Okružní 31, 638 00 Brno, after making arrangements by phone.

This Measure of a General Nature shall be posted for a period of 15 days.

RNDr. Pavel Klenovský
Director-General

Person responsible for accuracy: Mgr. Tomáš Hendrych

Posted on: 24 May 2017

Signature of the authorised person confirming posting: ............................................

23
Measure of a General Nature No 0111-OOP-C040-13

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